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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,904	09/18/2001	Jie Zhang	8747.82	8603
20551	7590	03/03/2006	EXAMINER	
THORPE NORTH & WESTERN, LLP. 8180 SOUTH 700 EAST, SUITE 200 SANDY, UT 84070			GEORGE, KONATA M	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/954,904	ZHANG ET AL.	
	Examiner Konata M. George	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 November 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-6,11-14,17 and 19-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6,11-14,17 and 19-32 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 18 September 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

Claims 1-6, 11-14, 17 and 19-32 are pending in this application.

### ***Action Summary***

1. The rejection of claims 1-6, 11-14, 17 and 19-28 under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims 1-8 of US Patent No. 6,245,347 B1, claims 1-7 of US Patent No. 6,488,959 B2 and claims 1-17 of US Patent No. 6,756,053 B2 is hereby withdrawn as applicant has supplied a terminal disclaimer.

### ***Priority***

2. The application claims priority to 09/878,558, but does not indicate the status as CIP, divisional or continuation as such; applicant is not entitled to priority to 09/878,558. Since four months has past since the filing date of the application and 16 months since the filing date of the prior application, applicant cannot correct by amendment of filing an ADS. Applicant must file a petition for unintentionally delayed submission of an amendment to priority claim. See MPEP Section 201.11 [R-3].

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-6, 11, 12, 20-26 and 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (US 5,658,583)

Zhang et al. discloses an apparatus for dermal administration of pharmaceuticals. Column 5, line 53 through column 6, line 15 discloses an apparatus comprising a drug reservoir and a heat-generating chamber. The heat-generating chamber can utilize a variety of known means for heating (electrical, chemical, etc.). A preferred embodiment comprises a medium made of carbon, iron, water and/or salt. The device also contains material that is permeable to air (i.e. microporous semi-permeable membranes). The device is a two-part system separated by a non-permeable wall. It would have been inherent to the user of the device to remove the device from the skin if it was too hot and the heat would cause skin problems.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 11-14, 17, 19, 22, 23 and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillman et al. (US 5,383,848) in view of Bettinger (US 5,427,585).

Hillman et al. discloses using a heat pack in combination with a transdermal device to promote permeation of a drug (column 25, lines 41-67). Column 9, lines 11-29 teach that analgesics can be used in the invention. The prior art does not teach a temperature modification apparatus or the claimed temperature.

Bettinger discloses heating the skin with an electrode and resistor (col. 3, lines 8-14). It is also taught that it is known in the art to apply moist heat in order to increase blood flow (col. 3, lines 15-21).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combine teachings of Bettinger that heating the skin with an electrode and resistor increases blood flow with the heated drug pack of Hillman et al. One of ordinary skill would have realized that by heating the skin to increase blood flow and administering an analgesic through the skin via heat would help facilitate the delivery of the drug. With respect to the claimed temperature ranges, absent a clear showing of criticality, the determination of particular temperature ranges is within the skill of the ordinary worker as part of the process of normal optimization to achieve the desired results of the claimed composition.

5. Claims 14, 19 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (US 5,658,583)

Zhang et al. discloses an apparatus for dermal administration of pharmaceuticals. Column 5, line 53 through column 6, line 15 discloses an apparatus comprising a drug reservoir and a heat-generating chamber. The heat-generating

chamber can utilize a variety of known means for heating (electrical, chemical, etc.). A preferred embodiment comprises a medium made of carbon, iron, water and/or salt. The device also contains material that is permeable to air (i.e. microporous semi-permeable membranes). The device is a two-part system separated by a non-permeable wall. The prior art does not teach the claimed temperature range.

With respect to the claimed temperature range, absent a clear showing of criticality, the determination of particular temperature range is within the skill of the ordinary worker as part of the process of normal optimization to achieve the desired results of the claimed composition.

### ***Conclusion***

6. Claims 1-6, 11-14, 17 and 19-32 are rejected.

### ***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for

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the organization where this application or proceeding is assigned are (571) 273-8000 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George



JOHN PAK  
PRIMARY EXAMINER  
GROUP 1600